

ANNEX 5 - Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected product: AMICA PROBE

FSCA-identifier: Our internal Ref. 36/15

Type of action products recall.

Date: 27.04.2015

Attention: Vigilance Competent Authority

Details on affected devices:

Disposable microwave applicator for interstitial or intraoperative use for microwave thermoablation of biological tissues.

APK16150T19V5 lotto 21331

APK16150T19V5 lotto 21816

APK16200T19V5 lotto 21549

www.hshospitalservice.com

Description of the problem:

Applicators are supposed to have to much fragile tip, due to a non-correct assembly. We consider applicators belonging to declared batch lots unsafe to be used. Tip breaking could occur applying bending forces during the use. If breaking occurs during insertion, procedure can not be executed.

Advise on action to be taken by the user:

Identifying and quarantining the device. Return back to HS Hospital Service SpA the probes belonging to the above mentioned lot numbers. HS Hospital Service SpA will replace them.

Contact reference person:

Laura Lenzi

Quality Assurance Responsible and Regulatory Affairs

HS Hospital Service SpA

Stefania Improta

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature

HS Hospital Service SpA

Sede legale/Registered Office: Via Zosimo, 13 - 00178 Roma, ITALY
Stabilimento di produzione/Factory: Via Angela Vacchi, 23/25 - 04011 Aprilia (Latina), ITALY
P.IVA 01296201005 - CF 04742650585 - Capitale Sociale €500.000,00 Inte.Vers.- REA di Roma n°1153156
Phone +39 06 9201961 - Fax +39 06 92727871 - Fax Orders + 39 9275519 - www.hshospitalservice.com



Management System
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ISO 9001:2008
www.tuv.com
ID: 910001034

